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EXAMINER	
LAMM, MARINA	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/661,693	PATHER ET AL.	
	Examiner	Art Unit	
	Marina Lamm	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,23,25-27,30-33,36,83,84,86,88,91,93 and 94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,23,25-27,30-33,36,83,84,86,88,91,93 and 94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/5/05; 7/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the amendment filed 07/05/05. Claims pending are 22, 23, 25-27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94. Claims 22, 30 and 86 have been amended. Claims 28, 29, 34, 35, 85, 87, 89, 90 and 95-97 have been cancelled.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 22, 23, 25-27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 10-12 of U.S. Patent No. **6,200,604** ('604). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention overlaps with that previously claimed. Specifically, claims 1-8 and 10-12 of '604 are directed to a method of using the product claimed in the instant claims. The product claims of the instant invention are obvious over the claims directed to a method of using such product because the method claims of '604 encompass the product claimed herein. The claims of '604 do not recite the specific medicament of the instant claims. However, the portion of the specification in '604 that supports the recited medicaments, includes fentanyl that would anticipate Claims 22 and 30 herein. Claims 22, 30 and those dependent thereon cannot be considered patentably distinct over Claims 1-8 and 10-12 of '604 when there is a specifically disclosed embodiment (i.e. Example 1) in the conflicting case that supports Claim 1 of that case and falls within the scope of Claims 22 and 30 herein because it would have been obvious to one having ordinary skill in the art to modify the composition of Claim 1 of '604 by selecting a specifically disclosed embodiment that supports that claim, i.e., the specific medicament disclosed therein. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment (example). A double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154

USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). See MPEP 804 (II) (B) (1).

3. Claims 22, 23, 25-27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-15 and 17-19 of copending Application No. **10/080,016** ('016). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention overlaps with that previously claimed. Specifically, claims 10-15 and 17-19 of '016 are directed to a method of using the product claimed in the instant claims. The product claims of the instant invention are obvious over the claims directed to a method of using such product because the method claims of '604 recite the product claimed herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 22, 23, 25-27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. **11/026,132** ('132) and claims 1-30 of copending Application No. **11/027,353** ('353). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention overlaps with that previously claimed. Thus,

both copending applications are directed to fentanyl effervescent dosage forms, which anticipate the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 22, 23, 25-27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. **11/026,327** ('327). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention overlaps with that previously claimed. Specifically, claims 1-22 of '327 are directed to a method of making the product claimed in the instant claims. The product claims of the instant invention are obvious over the claims directed to a method of making such product because the method claims of '327 recite the product claimed herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 22, 23, 25-27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-10 and 12-17 of copending Application No. **10/977,029** ('029). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention overlaps with that previously claimed. Specifically, claims 1-5, 7-10 and 12-17

of '029 are directed to a method of making the product claimed in the instant claims. The product claims of the instant invention are obvious over the claims directed to a method of making such product because the method claims of '029 encompass the product claimed herein. The claims of '029 do not recite the specific medicament of the instant claims. However, the portion of the specification in '029 that supports the recited medicaments, includes fentanyl that would anticipate Claims 22 and 30 herein. Claims 22, 30 and those dependent thereon cannot be considered patentably distinct over Claims 1-5, 7-10 and 12-17 of '029 when there is a specifically disclosed embodiment (i.e. Example 1) in the conflicting case that supports Claim 1 of that case and falls within the scope of Claims 22 and 30 herein because it would have been obvious to one having ordinary skill in the art to modify the composition of Claim 1 of '029 by selecting a specifically disclosed embodiment that supports that claim, i.e., the specific medicament disclosed therein. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment (example).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 22, 23, 26, 27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCarty (US 5,073,374) in view of Wehling et al. (WO 91/04757) and further in view of Streisand et al. ("Buccal absorption of fentanyl is pH-dependent in dogs", Anesthesiology, (1995 Mar), 82 (3), pp. 759-64).

McCarty teaches fast dissolving buccal tablets particularly useful for the administration of active ingredients that show poor bioavailability upon administration through non-parenteral modes. See Abstract. Such active ingredients include analgesics such as fentanyl. See col. 1, lines 14-30. The tablets of McCarty are placed in the buccal pouch of the oral cavity and allowed to dissolve. See col. 4, lines 3-7. The McCarty reference does not teach the effervescent couple of the instant claims. However, Wehling et al. teach effervescent dosage forms for direct oral administration (i.e. for direct insertion into the mouth of a patient), which comprise at least one systemically distributable ingredient (e.g. a drug), effervescent disintegration agents (a soluble acid source and a carbonate source) and adjuvants such as binders, flavors, colors, fillers, non-effervescent disintegrants, etc. See p. 3, lines 30-37; p. 11, lines 22-38; p. 12, lines 1-19; p. 14, lines 25-37; p. 15. Analgesics are among the drugs that can be administered in oral effervescent dosage forms of Wehling et al. See p. 9, line 29. The amount of the effervescent disintegration agents is 5-50% by weight, and the amount of either acid or carbonate source may exceed the amount of the other component. See p. 12, lines 20-36; p. 13, lines 3-12. "This may be useful to enhance taste and/or performance of a tablet containing an overage of either component." See p. 12, lines

36-38. The tablets of Wehling et al. dissolve in the mouth in between about 30 seconds and about 7 minutes. See p. 13, lines 13-24. Wehling et al. teach that the use of the effervescent disintegration agents provides the following benefits: masking the objectionable flavor of medicaments, facilitating the disintegration of the tablet and providing pleasant organoleptic sensation. See p. 6, lines 15-26. Further, such dosage forms are particularly useful in administration of medications to patients who cannot or will not chew, such as children and the elderly. See p. 4, lines 9-25. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the fast dissolving buccal fentanyl tablets of McCarty such that to employ effervescent disintegration agents. One having ordinary skill in the art would have been motivated to do this to obtain even faster dissolution as well as masking the objectionable flavor of medicaments and providing pleasant organoleptic sensation as suggested by Wehling et al. Further, while suggesting that the amount of either acid or carbonate source may exceed the amount of the other component in order to enhance taste and/or performance of a tablet containing an overage of either component, the Wehling reference does not explicitly teach the at least one pH adjusting substance which is a base as claimed herein. However, Streisand et al. teach that the buccal absorption, bioavailability and permeability of fentanyl are pH dependent and increase as the pH of the fentanyl solution becomes more basic, which is due to an increase in the fraction of unionized fentanyl. See Abstract; Discussion. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the

art at the time the invention was made to modify the teachings of Wehling et al. such as to employ the excess of the carbonate source (base). One having ordinary skill in the art would have been motivated to do this to obtain basic pH as which the buccal absorption, bioavailability and permeability of fentanyl increase, thus making the tablet more effective, as suggested by Streisand et al. With respect to Claims 93 and 94, which recite tablet "adapted for" gingival and sublingual administration, respectively, these types of administration are obvious variations of oral transmucosal administration. Therefore, Claims 93 and 94 don't recite any additional ingredients and/or characteristics, therefore, the combination of references discussed above meets the claimed limitations.

9. Claims 22, 23, 25-27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. ("Studies on formulations of fentanyl buccal adhesive tablets", Zhongguo Yiyao Gongye Zazhi, 1997, 28(3), 129-131[1]) in view of Wehling et al. (WO 91/04757) and further in view of Streisand et al. ("Buccal absorption of fentanyl is pH-dependent in dogs", Anesthesiology, (1995 Mar), 82 (3), pp. 759-64).

Chen et al. teach fentanyl citrate buccal adhesive tablets. See Abstract. Chen et al. do not teach the effervescent couple of the instant claims. However, Wehling et al. teach effervescent dosage forms for direct oral administration as discussed above. Streisand et al. teach that the buccal absorption, bioavailability and permeability of

[1] The full text of this article is not available at this time, but has been requested by the Examiner.

fentanyl are pH dependent and increase as the pH of the fentanyl solution becomes more basic as discussed above. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the adhesive buccal fentanyl tablets of Chen et al. such that to employ effervescent disintegration agents. One having ordinary skill in the art would have been motivated to do this to obtain even faster dissolution as well as masking the objectionable flavor of medicaments and providing pleasant organoleptic sensation as suggested by Wehling et al. Further, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Wehling et al. such as to employ the excess of the carbonate source (base). One having ordinary skill in the art would have been motivated to do this to obtain basic pH as which the buccal absorption, bioavailability and permeability of fentanyl increase, thus making the tablet more effective, as suggested by Streisand et al. With respect to Claims 93 and 94, which recite tablet "adapted for" gingival and sublingual administration, respectively, these types of administration are obvious variations of oral transmucosal administration. Therefore, Claims 93 and 94 don't recite any additional ingredients and/or characteristics, therefore, the combination of references discussed above meets the claimed limitations.

Response to Arguments

10. Applicant's arguments with respect to claims 22, 23, 25-27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. No claim is allowed at this time.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Weinberg et al. « Sublingual absorption of selected opioid analgesics », Clinical Pharmacology and Therapeutics, Sep. 1988, 44 (3), pp. 335-42.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm
10/14/05

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER